



NOV 10 2004

Dr. Christine E. Fastnaught  
National Barley Foods Council  
905 W. Riverside, Suite 501  
Spokane, WA 99201

RE: Health Claim Petition - To amend 21 CFR 101.81 to authorize a health claim relating barley  $\beta$ -glucan soluble fiber and barley foods containing  $\beta$ -glucan soluble fiber and coronary heart disease risk. Docket No. 2004P-0512

Dear Dr. Fastnaught:

This letter is in reference to the subject health claim petition, dated August 2, 2004, and received in the Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, Food and Drug Administration on August 3, 2004. We informed you on August 16, 2004, that the date by which FDA would either file or deny your petition is November 11, 2004. We have completed our initial review of this petition and are filing it as specified in section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (the act). The filing date is November 11, 2004. The Food and Drug Administration Docket number assigned for your petition is 2004P-0512. We will either publish a proposal in response to the petition or deny the petition within 90 days of the filing date, i.e., not later than February 9, 2005.

Sincerely yours,

Barbara O. Schneeman, Ph.D.

Director

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition

2004P-0512

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